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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,783	05/27/2004	Mohammed Moin Hussaini	146128CT	3782

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CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002

EXAMINER

HORWAT, JENNIFER A

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/709,783	Applicant(s) HUSSAINI ET AL.	
	Examiner Jennifer Horwat	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The finality of the Office action mailed is hereby withdrawn in view of the new ground of rejection set forth below.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 2, 5, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Onik, et al (US 4583538). Onik discloses a method for CT guided biopsies of the body. A respiratory gating device allows all scans and the biopsy to be obtained in the same phase of respiration (col 2, lines 20-22). The respiratory gating device gives a digital readout as to the patient's phase of respiration, which allows all scans to be taken in the same phase of inspiration (col 6, lines 43-46). Additionally, as stated in col 2, the biopsy may also be obtained in the same phase of respiration using the gating device. As further explained in claim 5, the guidance of the instrument, or end effector, may be gated as the device detects the degree of expansion of the patient's body such that the surgeon can determine identical degrees of respiration action. The path for the end effector is calculated from the skin entry point to the target coordinates (col 3, lines 12-20). Inherent in the use of a CT imaging system are moving a person within the scanning device and generating cross-sectional images.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Onik in view of Acker (US 6580938). Onik, as discussed above, substantially discloses the invention as claimed, including moving an end effector when a patient has a predetermined respiratory state. However, Onik fails to explicitly disclose the use of a threshold value. Acker also discloses advancing an end effector and further discloses the use of a threshold in determining whether or not the patient is in the predetermined respiratory state (col 4, lines 12-19). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Onik in light of the teachings in the reference by Acker to include a tolerance, or threshold value, to allow a range of acceptable data to be used instead of a single value representing respiration to allow movement of the end effector during a larger window of time for more efficient use of the device.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Onik in view of Hall, et al (US 6298257). Onik, as disclosed above, substantially discloses the invention as claimed. However, Onik fails to disclose that the end effector is moved at a predetermined speed. Hall discloses a method of moving an end effector wherein a computer calculates and induces movement of the end effector. The catheter may be automatically advanced and withdrawn by a computer controlled mechanism (col 3,

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lines 33-35). Therefore, the speed at which the end effector is moved is predetermined by the computer. Additionally, as the body moves due to respiration, Hall discloses that positional data may be obtained so that positional data may be coordinated with timing data (col 6, lines 29-33). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Onik in light of the teachings in the reference by Hall to include computer controlled movement of the end effector, as this would provide improved precision and control of the movements and remove any hand tremor from the surgeon, which provides improved patient results.

7. Claims 6, 8-11, 14-17, 19, 20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onik, et al (US 4583538) in view of Hall, et al (US 6298257).

Onik discloses a method for CT guided biopsies of the body. A respiratory gating device allows all scans and the biopsy to be obtained in the same phase of respiration (col 2, lines 20-22). The respiratory gating device gives a digital readout as to the patient's phase of respiration, which allows all of the scans to be taken in the same phase of inspiration (col 6, lines 43-46). Additionally, as stated in col 2, the biopsy may also be obtained in the same phase of respiration using the gating device. As further explained in claim 5, the guidance of the instrument, or end effector, may be gated as the device detects the degree of expansion of the patient's body such that the surgeon can determine identical degrees of respiration action. The path for the end effector is calculated from the skin entry point to the target coordinates (col 3, lines 12-20).

Inherent in the use of a CT imaging system are moving a person within the scanning

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device and generating cross-sectional images. A computer control the movement of a patient within the CT bore to obtain images at different axial positions.

However, Onik fails to disclose that the end effector movement is controlled by a computer. Hall discloses a method of moving an end effector wherein a computer calculates and induces movement of the end effector. The catheter may be automatically advanced and withdrawn by a computer controlled mechanism (col 3, lines 33-35). Therefore, the speed at which the end effector is moved is predetermined by the computer. The computer controlled mechanism can orient the catheter to follow a predetermined trajectory. A location device is included to aid in locating the catheter and registering the catheter with other images (col 6, lines 27-30). Further, Hall discloses that imaging may be done, such as by fluoroscopy, to aid in localization (col 5, lines 48-50). Additionally, as the body moves due to respiration, Hall discloses that positional data may be obtained so that positional data may be coordinated with timing data (col 6, lines 29-33). In combination with Onik, Onik provides the gating signal for movement only when the patient is in the predetermined respiratory state, as discussed above. It is inherent in the use of a computer and computer processor that all functions controlled by the computer are controlled by code for the desired function of the computer. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Onik in light of the teachings in the reference by Hall to include computer controlled movement of the end effector, as this would provide improved precision and control of the movements and remove any hand tremor from the surgeon, which provides improved patient results.

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8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Onik in view of Hall as applied to claim 6 above, and further in view of Schweikard, et al (US 6144875). The system disclosed by Onik in view of Hall uses external positional markers to monitor the respiration state of the patient and does not explicitly disclose the use of infrared to monitor respiration. Schweikard discloses an apparatus and a method for compensating for respiratory and patient motion during treatment using infrared to track external markers (col 6, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Onik in view of Hall with the teachings in the reference by Schweikard, as it is well known in the medical imaging art to substitute one type of detector for another to serve the same purpose.

9. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onik in view of Hall as applied to claim 6 above, and further in view of Acker (US 6580938). Onik in view of Hall, as discussed above, substantially discloses the invention as claimed, including moving an end effector when a patient has a predetermined respiratory state. However, Onik in view of Hall fails to explicitly disclose the use of a threshold value. Acker also discloses advancing an end effector and further discloses the use of a threshold in determining whether or not the patient is in the predetermined respiratory state (col 4, lines 12-19). In combination with Onik and Hall, the computer controlled advancement would be modified to include such a threshold. It is inherent in the use of a computer and computer processor that all functions controlled by the computer are controlled by code for the desired function of

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the computer. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Onik in view of Hall in light of the teachings in the reference by Acker to include a tolerance, or threshold value, to allow a range of acceptable data to be used instead of a single value representing respiration to allow movement of the end effector during a larger window of time for more efficient use of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jah
8/28/06


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700